K083302

510(k) Summary

AUG 0 3 2009

As Required by 21 section 807.92 (c)

1-Submitter Name: Everyway Medical Instruments Co., Ltd
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5-Contact Person: Mr Robert Tu (General Manager)
6-Date summary prepared: July 28, 2009
7- Official Correspondent: Mansour Consulting LLC
8- Address: 845 Aronson Lake Court. Roswell, GA 30075 USA
9- Phone: 678-908-8180
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11- Contact Person: Jay Mansour, President
12-Device Trade or Proprietary Name: Lifecare electrodes
13-Device Common or usual name: Lifecare Neurostimulation electrodes
14-Device Classification Name: Cutaneous electrode
15-Substantial Equivalency is claimed against the following device:

- Lifecare electrodes from Everyway Medical Instruments Co., Ltd. 510k# K012463
- Gemore electrodes from Gemore Technology Co. Ltd, 510k# K062675

16-Description of the Device:

The Lifecare electrodes are constructed with four basic components: a wire; an insulation backing; a conductive surface; and a conductive adhesive gel. The devices function by conducting an electrical signal from a neurostimulation device through the wire. The signal is then dispersed from the wire across the conductive surface. Finally the signal is transmitted from the conductive surface through the conductive adhesive gel to the surface of the patient's skin.

Everyway Self Adhesive Electrode, Wire series are non-sterile, disposable laminated, flexible structures composed of material commonly used in this application:

First Layer – White spun laced nonwoven tape or white thick Polyethylene foam or a polypropylene substrate, coated with biocompatible adhesive.
Second Layer – Conductive plastic film
Third Layer – Biocompatible conductive hydrogel coupling media

The electrodes are designed for single-patient/single application use. Because of the adhesive nature of the biocompatible hydrogel, no securing materials are required to secure the device to the patient's skin. The electrode has one type of connection point that can be used to connect the stimulation device the electrodes. This connection point is compatible with standard, marketed Neurostimulation devices.

For the electrical connection, Everyway provides one type of connection:

Wire Series – Lead wire assembly – 4.5" – 6" wire with 0.080 in. diameter female socket connected to one side of the wire.

These electrodes are: TKF5050 (5x5 cm square), TKF4040 (4x4 cm square), TKF50D (5cm round), TKF75D (7.5cm round), TKF4060V (4x6cm oval), TKF50100V (5x10cm oval), TKF4080 (4x8cm rectangle) and TKF50100 (5x10cm rectangle)

17-Intended use of the device: (refer to FDA form attached)

The Lifecare electrodes are intended for use with transcutaneous neurostimulation devices as over the counter. Some common type of neurostimulation devices include, but are not limited to, TENS devices and EMS devices. Transcutaneous neurostimulation electrodes are passive devices serving as an interface between a patient's skin and a neurostimulation device.

18-Safety and Effectiveness of the device:

This device is safe and effective as the predicate devices cited above as detailed within this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Everyway Medical Instrument Co., Ltd.
% Mansour Consulting LLC
Mr. Jay Mansour
845 Aronson Lake Court
Roswell, Georgia 30075

AUG 0 3 2009

Re: K083302
Trade Name: Lifecare Electrodes
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrodes
Regulatory Class: II
Product Code: GXY
Dated: June 22, 2009
Received: June 24, 2009

Dear Mr. Mansour:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K083302

Device Name: Lifecare Electrodes

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Prescription Use _____ AND/OR Over-The-Counter Use ✓
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K083302